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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/972,031	10/04/2001	Eugeni Namsaraev	STAN-202	2881

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EXAMINER

JOHANNSEN, DIANA B

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 07/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/972,031

Applicant(s)

NAMSARAEV ET AL.

Examiner

Diana B. Johannsen

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1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 April 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) 34-44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-33 and 45 is/are rejected.
- 7) ☒ Claim(s) 8 and 9 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 0402.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

1. It is noted that the paper and computer readable forms of the Sequence Listing filed with the instant application on October 4, 2001 have been entered.

Priority

2. It is noted that provisional application 60/239,068, filed October 4, 2000, provides basis for Applicants' claimed invention. Accordingly, the effective filing date of the instant application is October 4, 2000.

Election/Restriction

3. Applicant's election without traverse of Group I, claims 1-33 and 45, in the Response filed April 14, 2003 is acknowledged.

4. Claims 34-44 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the Response filed April 14, 2003.

Specification

5. The use of the trademarks ULTRAHYB™ and HYBSPEED™ has been noted in this application. The trademarks should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Objections

6. Claims 8-9 are objected to because of the following informalities: claim 8 includes the recitation "a molecule of DNA molecule" (rather than, e.g., "a molecule of DNA" or "a DNA molecule"). Appropriate correction is required.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-33 are indefinite because it is unclear as to how the practice of the method steps recited in the claims allows one to achieve the objective of "discriminating among a plurality of nucleic acid targets" as recited in the preamble of claim 1. The claims merely require a step of "identifying differences in the extent of nucleic acid duplex formation," and it is unclear as to whether this step of "identifying differences" is equivalent to "discriminating" among targets, or whether an additional step or steps to achieve "discriminating" are required. Accordingly, the claims are vague and indefinite, and it is unclear as to whether the claims are intended to be drawn to a method for discrimination among nucleic acid targets or to a method of identifying differences in duplex formation.

Claims 1-33 are indefinite over the recitation of the limitation "said duplexes" in claim 1, because there is insufficient antecedent basis for this limitation in the claim. It

is also noted that dependent claims 6-8, 12-14, 25, and 33 also refer to "said duplexes" and/or "said each of said duplexes" or "said nucleic acid duplexes"; while claim 1 as presently written provides antecedent basis for these recitations (by virtue of reciting "each of said duplexes"), an amendment of claim 1 to overcome the above rejection may also necessitate amendment of these dependent claims.

Claims 10-11 are indefinite because it is unclear as to whether the recitations "at least 16 nucleotides in length" (in claim 10) and "no more than 30 nucleotides in length" (in claim 11) are intended to refer to the length required for "at least one of said targets" or to the length of the "region of complementarity." Accordingly, the manner in which claims 10-11 further limit claim 1 cannot be ascertained.

Claims 23-24 are indefinite over the recitation of the limitation "said common probe" in claim 23 because there is insufficient antecedent basis for this limitation in the claims. While claim 1, from which claim 23 depends, refers to "at least one common nucleic acid probe," the claim does not refer to or recite a single particular "common probe."

Claims 26, 29, 30 and 33 are indefinite over the recitation of the limitation "said hybridization reactions" in each of the claims because there is insufficient antecedent basis for this recitation in the claims.

Claim 27 is indefinite over the recitation of the limitation "said common probe" because there is insufficient antecedent basis for this limitation in the claims. While claim 1, from which claim 27 depends, refers to "at least one common nucleic acid probe," the claim does not refer to or recite a single particular "common probe."

Claim 28 is indefinite over the recitation of the limitation "said probe" because there is insufficient antecedent basis for this limitation in the claims. While claim 1, from which claim 27 depends, refers to "at least one common nucleic acid probe," the claim does not refer to or recite a single particular "common probe."

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claims 1-33 and 45 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Cronin et al (U.S. 6,027,880 [2/2000; filed 10/1995]).

Cronin et al disclose methods of detecting and discriminating among various nucleic acid targets by hybridization of target molecules with arrays of probes, wherein relative hybridization intensities indicate differences in the extent of duplex formation (see entire reference, particularly col 2, line 8-col 3, line 55; col 40, line 66-col 41, line 63; col 45, line 14-col 51, line 60; Figs 1, 3, 10-11). Cronin et al disclose the use in hybridization buffer of agents that "improve discrimination between perfectly matched targets and single-base mismatches," including tetramethylammonium chloride and betaine (col 59, line 61-col 60, line 6), and exemplify the use of one such an agent,

cetyltrimethylammonium bromide (CTAB), that is specifically recited in Applicants' claims as a preferred specific association enhancer (see col 47, line 5-col 48, line 39, particularly col 47, lines 49-50 and 57).

With respect to claims 6-9 and 17-24, Cronin et al disclose both DNA and RNA probes and modified forms thereof (see, e.g., col 11, line 59-col 12, line 5) and target molecules comprising genomic DNA, RNA (including mRNA), and cDNA (see col 37, line 66-col 38, line 30). Cronin et al specifically disclose molecules obtained from or "derived" from human sources (see, e.g., col 38, lines 1-8). Further, regarding claims 8-9, it is noted that Cronin et al disclose the use of any modified forms of DNA or RNA probes, including probes modified at the 2' carbon of ribose (col 11, line 66-col 12, line 5). Regarding claims 10-14, Cronin et al disclose that preferred probes are 9-21 nucleotides in length and fully complementary to their targets (see, e.g., col 11, lines 11-14); accordingly, Cronin et al disclose probes meeting the requirements of the claims. It is also noted that Cronin et al disclose reference sequences of a variety of lengths (see, e.g., col 10, lines 16-26). With respect to claims 15-16, Cronin et al disclose the use of chips comprising thousands of probes, each of which detects a different target (see, e.g., col 12, lines 26-61). Regarding claims 25-26, Cronin et al disclose both single phase and common hybridization reactions (see, e.g., col 24, line 64-col 25, line 8). Regarding claim 29, it is noted that Cronin et al exemplify the use of 1 mM and 10 mM CTAB, and thereby exemplify the use of less than 0.7 M of one of the particular salts recited in Applicants' claims. With respect to claim 30, Cronin et al also disclose and exemplify hybridization at temperatures meeting the requirements of the claim (see,

e.g., col 47, lines 56-60). Regarding claim 31, Cronin et al disclose and exemplify differentiating single base differences (see, e.g., col 45, line 16-col 51, line 10).

Regarding claims 32-33, Cronin et al disclose post-hybridization washing with salt-containing buffer (see, e.g., col 47, lines 58-60); such washing accomplishes both removal of enhancer and separation of duplexes from hybridization reactions.

Regarding claim 45, it is noted that while Cronin et al do not state that methods employing CTAB or other enhancers "increase the specific association rate" of molecules, Cronin et al disclose and exemplify methods comprising steps meeting the requirements of the claims. Accordingly, Cronin et al anticipate claims 1-33 and 45.

11. Claims 1-33 and 45 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Cronin et al (U.S. 6,027,880 [2/2000; filed 10/1995]).

Cronin et al disclose methods of detecting and discriminating among various nucleic acid targets by hybridization of target molecules with arrays of probes, wherein relative hybridization intensities indicate differences in the extent of duplex formation (see entire reference, particularly col 2, line 8-col 3, line 55; col 40, line 66-col 41, line 63; col 45, line 14-col 51, line 60; Figs 1, 3, 10-11). Cronin et al disclose the use in hybridization buffer of agents that "improve discrimination between perfectly matched targets and single-base mismatches," including tetramethylammonium chloride and betaine (col 59, line 61-col 60, line 6), and exemplify the use of one such an agent, cetyltrimethylammonium bromide (CTAB), that is specifically recited in Applicants' claims as a preferred specific association enhancer (see col 47, line 5-col 48, line 39, particularly col 47, lines 49-50 and 57).

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Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Pontius et al (Proc. Natl. Acad. Sci. USA 88:8237-8241 [9/1991]) disclose that it is an inherent property of CTAB that it enhances DNA renaturation (see entire reference).

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is 703/305-0761. The examiner can normally be reached on Monday-Friday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached at 703/308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are 703/872-9306 for regular communications and 703/872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703/308-0196.

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A handwritten signature in black ink, reading "Diana B. Johannsen". The signature is written in a cursive style with a long, sweeping underline.

Diana B. Johannsen

July 28, 2003